§170.315(a)(12) Family health history

2015 Edition CCGs

Version 1.4 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-22-2015
1.1	Added clarification for the testing and certification of “familial concepts or expressions”.	12-18-2015
1.2	Removed “unstructured/free text recording” clarification.	03-18-2016
1.3	Further clarification provided for the structured coding and representation of familial relationship.	02-17-2017
1.4	Updated the Security requirements per 21st Century Cures Act.	06-15-2020

Regulation Text

Regulation Text

§170.315 (a)(12) *Family health history—*

Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in §170.207(a)(4).

Standard(s) Referenced

Applies to entire criterion

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release

Certification Companion Guide: Family health history

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(a)(12). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(a) "paragraph (a)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (a) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be presented once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.
- § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))

- Audit reports (§ 170.315(d)(3))
- Amendments (§ 170.315(d)(4))
- Automatic access time-out (§ 170.315(d)(5))
- Emergency access (§ 170.315(d)(6))
- End-user device encryption (§ 170.315(d)(7))
- Encrypt authentication credentials (§ 170.315(d)(12))
- Multi-factor Authentication (MFA) (§ 170.315(d)(13))

- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Technical outcome – The health IT permits users to record, change, and access a patient's family health history (FHH) according to the September 2015 Release of SNOMED CT®, U.S. Edition.

Clarifications:

- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [80 FR 62612]
- We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  - The SNOMED CT® OID: 2.16.840.1.113883.6.96. [80 FR 62612]
- Developers have the discretion to code associated FHH questions in the manner they choose (e.g., including but not limited to LOINC®). [80 FR 62624]

- At a minimum, the health IT must enable a user to record, change, and access information about a patient's first degree relative within the said patient's record. However, health IT does not need be able to access the records of the patient's first degree relatives for certification. [see 77 FR 54174]
- Our intent with "familial concepts and expressions" is to focus on the first degree relative's diagnosis. For testing and certification, at a minimum, a system must be able to demonstrate that it can record, change, and access this diagnosis and the familial relationship in a codified manner using SNOMED CT®. The developer has the flexibility to determine how the system will represent the codified familial relationship, pre- or post-coordinated.

Content last reviewed on June 22, 2020